

**RULES  
OF  
THE TENNESSEE DEPARTMENT OF MENTAL HEALTH  
AND DEVELOPMENTAL DISABILITIES**

**CHAPTER 0940-5-42  
MINIMUM PROGRAM REQUIREMENTS FOR ALCOHOL AND DRUG ABUSE  
NON-RESIDENTIAL OPIATE TREATMENT FACILITIES**

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**0940-5-42-.01 DEFINITIONS.**

- (1) Abuse. The infliction of physical pain, injury, or mental anguish on a client by a caretaker. Abuse includes "exploitation" as defined by these rules.
- (2) A.D.A. The Americans with Disabilities Act.
- (3) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.
- (4) Aftercare Plan. A plan which specifies, as appropriate, referral for further counseling and/or treatment services at another level of care, the type of contact, planned frequency of contact and the staff responsible for referrals. The focus of the aftercare phase is to ensure the maintenance of gains made and the ongoing achievement of long term goals.
- (5) Alcohol and Other Drugs of Abuse Services:
  - (a) Treatment Services - Formal, organized services for persons who have abused alcohol and/or other drugs. These services are designed to alter specific physical, mental or social functions of persons under treatment by reducing client disability or discomfort, and ameliorate the signs or symptoms caused by alcohol and/or other drug abuse.
  - (b) Rehabilitation or Habilitation Services - A range of services for persons who have abused alcohol and/or other drugs. These services may include an array of counseling, vocational, social and/or educational services aimed at restoring overall well-being, health and ability to engage in rewarding and/or productive activities.
- (6) Assessment. A documented evaluation of a client for the purpose of determining treatment and/or rehabilitation or habilitation needs. An assessment may, but does not necessarily, include examination and tests determined to be necessary by the treatment staff, based on the presenting problems and symptoms of the individual client.
- (7) Board. The Board for Licensing Health Care Facilities.
- (8) Business Occupancies. Those facilities used for the transaction of business (other than that covered under mercantile), for the keeping of accounts and records, and similar purposes.

(Rule 0940-5-42-.01, continued)

- (9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a resident, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a resident where cardiac or respiratory arrest has occurred or is believed to be imminent.
- (10) Case Management. A series of actions based on the relationship between a person and a case manager, which assist the person and his/her family to access clinical treatment, housing, education, employment, financial, medical, and other support services that the person and the case manager deem necessary for his/her successful community living.
- (11) Central Registry. An electronic system used to register clients currently receiving opioid replacement treatment at a NRNTF. The Department or SNA may require NRNTFs to initiate a clearance inquiry and client registration into an approved central registry for the purpose of gathering program information, performance data and to prevent simultaneous enrollment in other NRNTFs.
- (12) Chief Executive Officer or Director. The person appointed, designated, or hired by the governing body to be responsible for the day-to-day operation of the facility or facilities operated by the licensee.
- (13) Civil Rights. The rights of personal liberty guaranteed to citizens by the Constitutions of the United States and the State of Tennessee, and by federal and state statutes.
- (14) Client. The individual who is the direct recipient of the services provided by the facility subject to the licensure jurisdiction of the Tennessee Department of Health.
- (15) Commissioner. The Commissioner of Health or his/her designee.
- (16) Counseling Session. Therapeutic discussion between client(s) and a facility counselor for a period of no less than thirty (30) minutes designed to address client addiction issues or coping strategies and treatment plans.
- (17) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:
  - (a) the action(s) implemented to prevent the reoccurrence of the unusual event,
  - (b) the time frames for the action(s) to be implemented,
  - (c) the person(s) designated to implement and monitor the action(s), and
  - (d) the strategies for the measurements of effectiveness to be established.
- (18) DEA. The United States Drug Enforcement Agency.
- (19) Department. The Tennessee Department of Health.
- (20) Detoxification. Medical and non-medical procedures resulting in the systematic reduction of the amount of a toxic agent in the body or the elimination of a toxic agent from the body.
- (21) Do Not Resuscitate (DNR) Order. An order entered by the client's treating physician in the client's medical records which states that in the event the client suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain

(Rule 0940-5-42-.01, continued)

limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

- (22) Drug Abuse. A condition characterized by the continuous or episodic use of a drug or drugs resulting in impairment of the user's physical, mental, emotional, or social well-being, vocational impairment, psychological dependence or pathological patterns of use as defined in currently accepted diagnostic nomenclature.
- (23) DSM. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV is the fourth edition of the manual).
- (24) Exploitation. The improper use by a caretaker of funds which have been paid by a governmental agency to a patient or client or to the caretaker for the use or care of the patient or client; the "borrowing" or improper solicitation, use or conversion of any monies or property paid by a person or entity to a patient or client or to the caretaker for the use of or care of the client; engaging in sexual contact or sexual penetration with a patient or client by the caretaker; coercion, conspiring with or aiding a patient or client to engage in any criminal activity by the caretaker.
- (25) Facility. A treatment resource, counseling center, or other entity providing alcohol and drug abuse services.
- (26) FDA. The United States Food and Drug Administration.
- (27) Governing Body. The person or persons with primary legal authority and responsibility for the overall operation of the facility and to whom a director/chief executive officer is responsible. Depending upon the organizational structure, this body may be an owner or owners, a board of directors or other governing members of the licensee, or, state, city or county officials appointed by the licensee, etc. The Governing Body maintains and controls the program and is legally responsible for the operation.
- (28) Inspection. Any examination by the Department or its representatives of a provider, including but not limited to the premises, staff, persons in care, and documents pertinent to initial and continued licensing, so that the Department may determine whether a provider is operating in compliance with licensing requirements or has violated any licensing requirements. The term inspection includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to licensing requirements.
- (29) LAAM. The acronym for levo-alpha-acetyl-methadol or levomethadyl acetate hydrochloride (trade name ORLAAM). LAAM is a synthetic opioid agonist which has been approved by the FDA for the maintenance treatment of opiate addiction.
- (30) Licensee. The proprietorship, partnership, association, governmental agency or corporation which operates a facility under the licensure jurisdiction of the Department.
- (31) Licensure. The process by which an agency of government grants permission, to persons or health care facilities meeting qualifications, to engage in a given occupation and/or use a particular title.
- (32) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.
- (33) Maintenance Treatment. The dispensing of a narcotic drug, at relatively stable dosage levels, for a continuous, open-ended period deemed medically necessary by a program

(Rule 0940-5-42-.01, continued)

physician or medical director, in the treatment of an individual for dependence on heroin or other opiate-like drugs.

- (34) **Medical Director.** A physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who has been designated by the governing body of the NTF to be responsible for the administration of all medical services performed by the NTF, including compliance with all federal, state, and local laws and rules regarding medical treatment of narcotic addiction. The medical director shall have the experience and credentials specified in subparagraph 0940-5-42-.04 (5) (a) of these rules.
- (35) **Medically Futile Treatment.** Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident.
- (36) **Medical Record.** Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to residents, patients or clients.
- (37) **Methadone.** A synthetic narcotic agonist which has been approved by the FDA for detoxification and maintenance treatment of narcotic addiction (trade name Dolophine).
- (38) **Multidisciplinary Treatment Team (Treatment Team).** Professionals which may include a physician, nurse, alcohol and drug abuse counselor and mental health professionals who assess client progress.
- (39) **Narcotic Dependent.** An individual who physiologically needs heroin or other opiate-like drugs to prevent the onset of signs of withdrawal.
- (40) **Narcotic Treatment Facilities (NTF).** Any program for chronic heroin or other opiate-like drug users that administers narcotic drugs under physicians' orders either for detoxification purposes or for maintenance treatment in a rehabilitative context; the term facility includes any program or clinic licensed by the Department to operate as a Non-Residential Narcotic Treatment Facility (NRNTF).
- (41) **Non-Residential Narcotic Treatment Facility (NRNTF).** A non-residential narcotic treatment facility which provides a combination of medical, mental health, and social services for treating the opiate dependent client with the goal of the individual becoming free from any drug which is not medically indicated. Non-residential narcotic treatment services in Tennessee consist of three (3) treatment modalities as follows: Thirty (30) Day Detoxification Treatment, Long Term Detoxification Program (180 day program), and Narcotic Replacement Maintenance Treatment Program. Clients are admitted to the various modalities based upon client requests and admission criteria defined in the state and federal rules, as medically appropriate. Each modality is further defined as follows:
  - (a) **Thirty (30) Day Detoxification Treatment.** A period of continuous detoxification treatment with narcotic replacement therapy not to exceed thirty (30) days in length for the purpose of assisting the opiate-dependent client in reaching a drug-free state. There must be at least thirty (30) days between thirty (30) day treatment episodes. An episode of thirty (30) day detoxification is any length of time in which the client receives narcotic replacement therapy for three (3) or more days.

(Rule 0940-5-42-.01, continued)

- (b) Long Term Detoxification Program. A period of narcotic replacement therapy services or programs in Tennessee not to exceed 180 days. Clients who have completed the 180 day detoxification must wait seven (7) days between Long Term Detoxification Program episodes.
  - (c) Narcotic Replacement Maintenance Treatment Program. That period of continuous open-ended narcotic replacement treatment services as deemed necessary by the program physician/medical director. Clients will be admitted or re-admitted to this modality only after careful clinical evaluation by a multidisciplinary team.
- (42) Narcotic Replacement Treatment. The substitution of a prescription drug which has been approved by the FDA for the treatment of opiate addiction to heroin or other opiate-like drugs.
  - (43) Neglect. The deprivation of services, including adequate and nutritious food and drink, by a caretaker, which are necessary to maintain the health and welfare of the client. Neglect includes "exploitation" as defined by these rules.
  - (44) Observed Testing. Testing conducted and witnessed by a facility staff person to ensure against falsification or tampering of results of a drug screen.
  - (45) On-Duty/On-Site. A staff person who is on the facility's premises and has the obligation to carry out any job responsibilities designated in his/her job description.
  - (46) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.
  - (47) Philosophy of Opiate Dependence and Treatment. A narrative overview as to why persons become opiate dependent which addresses the social, emotional, physiological, and spiritual aspects of dependency. The overview must further address how narcotic treatment and its ancillary services help the opiate dependent person in their recovery.
  - (48) Physical Holding. The use of body contact by staff to prevent the client's behavior from becoming dangerous to self, others, or property.
  - (49) Physician. A physician is a person who is duly licensed in Tennessee to practice medicine by the Tennessee Board of Medical Examiners or by the Tennessee Board of Osteopathic Examination.
  - (50) Policies and Procedures Manual. A document that describes the philosophy, services, organization, policies, and procedures for implementing services to the clients of a facility.
  - (51) Program Director (or "Sponsor"). The person designated by the program's governing body who is responsible for the operation of the program, for overall compliance with federal, state and local laws and regulations regarding the operation of narcotic treatment programs, and for all program employees including practitioners, agents, or other persons providing services at the program.
  - (52) Program Physician. Any physician, including the medical director, who is employed by a NTF to provide medical services to clients. Any program physician who is not a medical director must work under the supervision of the program's medical director.

(Rule 0940-5-42-.01, continued)

- (53) Psychiatrist. A physician who specializes in the assessment and treatment of individuals having psychiatric disorders, is certified by the American Board of Psychiatry and Neurology or has the documented equivalent in education and training, and who is fully licensed to practice medicine in the State of Tennessee.
- (54) Qualified Alcohol and Other Drugs of Abuse Personnel. Persons who meet the criteria described in items (a), (b) and (c) as follows:
  - (a) Currently meet one (1) of the following conditions:
    - 1. Licensed or certified by the State of Tennessee as a physician, registered nurse, practical nurse, clinical or counseling psychologist, psychological examiner, social worker, alcohol and other drugs of abuse counselor, teacher, professional counselor, or marital and family therapist, or, if there is no applicable licensure or certification by the state, has a bachelor's degree or above in a behavioral science or human development related area; or
    - 2. Actively engaged in a recognized course of study or other formal process for meeting the criteria of part (1) of subparagraph (a) above, and directly supervised by a staff person who meets the criteria in part (1) of subparagraph (a) above, who is trained and qualified as described in subparagraphs (b) and (c) below, and who has a minimum of two (2) years experience in his/her area of practice; and
  - (b) Are qualified by education and/or experience for the specific duties of their position; and
  - (c) Are trained in alcohol or other drug specific information or skills. (Examples of types of training include, but are not limited to, alcohol or other drug specific services, workshops, substance abuse schools, academic coursework and internships, field placement, or residencies).
- (55) Random Testing. Drug screens conducted by the facility that lack a definite pattern of who and when clients are selected for testing; indiscriminate testing.
- (56) Relapse. The failure of a client to maintain abstinence from illicit drug use verified through drug screen.
- (57) Reputable and Responsible Character. Possession of a personal, professional and/or business history and practice that recommends the licensed owner or operator or applicant be entrusted with the responsibility for persons with mental illness and those particularly susceptible to participation in illegal, medically dangerous, unhealthy practices and financial and sexual and other forms of exploitation. Personal, professional and/or business histories and practices containing evidence of the operation of substandard facilities, violation of the professional and business licensing laws and regulations of the State of Tennessee and the United States of America are presumed inconsistent with a "reputable and responsible character".
- (58) State Board of Pharmacy. The Board created to regulate the practice of pharmacy pursuant to T.C.A. §63-10-501.
- (59) State Narcotic Authority (SNA). The Tennessee Department of Health or any agency that has been designated in Tennessee to exercise the responsibility and authority for governing

(Rule 0940-5-42-.01, continued)

the treatment of narcotic addiction with a narcotic drug in accordance with all applicable state and federal regulations.

- (60) Treatment. A broad range of services including outreach, identification, assessment, diagnosis, detoxification, therapy, medical services, lectures/seminars, group process, social services, and follow-up or aftercare for individuals with alcohol and other drug problems. The overall goal is to eliminate the alcohol and drug use as a contributing factor to physical, psychological and social dysfunction and to arrest or reverse the progress of any associated problems.
- (61) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.
- (62) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.
- (63) Volunteer. A person who is not paid by the licensee and whose varied skills are used by the licensee to support and supplement the efforts of the paid facility staff.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Amendment filed April 11, 2003; effective June 25, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

#### **0940-5-42-.02 LICENSING PROCEDURES.**

- (1) No person, partnership, association, corporation, or state, county or local government unit, or division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any NRNTF, as defined, without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the NRNTF.
- (2) In order to make application for a license:
  - (a) The applicant shall submit an application on a form provided by the Department along with a copy of the Certificate of Need (CON), if necessary, issued by the Tennessee Health Facilities Commission or any other applicable state agency. Any condition placed on the CON will also be placed on the license. The written application for operation of a NRNTF must be filed simultaneously with the Substance Abuse and Mental Health Services Administration and the DEA, and/or any other applicable federal agencies.
  - (b) Each initial and renewal application for licensure shall be submitted with the appropriate fee or fees. All fees submitted are nonrefundable. The fee rate is based on the number of distinct facility categories to be operated at each non-residential site. Any applicant who files during the fiscal year must pay the full license fee. A fee must be submitted for each facility at each site for which licensure is being sought under the following schedule:
    - 1. The Annual License Fee for each NRNTF is \$600.00

(Rule 0940-5-42-.02, continued)

2. An additional fee of \$150.00 is required for each additional distinct facility category to be licensed in conjunction with the above.
- (c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Clients shall not be admitted to the NRNTF until a license has been issued. Providing narcotic replacement treatment services without a license is unlawful and will result in civil and/or criminal sanctions pursuant to T.C.A. §68-11-213. A license shall not be issued until the facility is in substantial compliance with these rules and regulations.
- (d) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and the review process.
- (e) The applicant must prove the ability to meet the financial needs of the facility.
- (3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.
  - (a) For the purposes of licensing, the licensee of a NRNTF has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the NRNTF's operation is transferred.
  - (b) A change of ownership occurs whenever there is a change in the legal structure by which the NRNTF is owned and operated.
  - (c) Transactions constituting a change of ownership include, but are not limited to, the following:
    1. Transfer of the facility's legal title;
    2. Lease of the facility's operations;
    3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;
    4. One partnership is replaced by another through the removal, addition or substitution of a partner;
    5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;
    6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;
    7. The consolidation of a corporate facility owner with one or more corporations; or
    8. Transfers between levels of government.
  - (d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:



(Rule 0940-5-42-.02, continued)

1. Changes in the membership of a corporate board of directors or board of trustees;
  2. Two (2) or more corporations merge and the originally-licensed corporation survives;
  3. Changes in the membership of a non-profit corporation;
  4. Transfers between departments of the same level of government; or
  5. Corporate stock transfers or sales, even when a controlling interest.
- (e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.
- (f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.
- (4) To be eligible for a license or renewal of a license, each NRNTF shall be periodically inspected for compliance with these rules. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the Department.
- (5) Every facility owner or operator shall designate a distinctive name for the facility which shall be on the application for a license. The name of a facility shall not be changed without first notifying the Department in writing. The change will be made when renewal of license is due.
- (6) A separate license shall be required for each facility when more than one facility is operated under the same management or ownership.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-213, and 68-11-216 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

#### **0940-5-42-.03 DISCIPLINARY PROCEDURES.**

- (1) The board may suspend or revoke a license for:
- (a) Violation of federal statutes or rules.
  - (b) Violation of state statutes or the rules as set forth in this chapter.
  - (c) Permitting, aiding or abetting the commission of any illegal act in the NRNTF.
  - (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the clients of the NRNTF.
  - (e) Failure to renew the license.

(Rule 0940-5-42-.03, continued)

- (2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:
  - (a) The degree of sanctions necessary to ensure immediate and continued compliance;
  - (b) The character and degree of impact of the violation on the health, safety and welfare of the clients of the facility;
  - (c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,
  - (d) Any prior violations by the facility of statutes, regulations or orders of the board.
- (3) When a NRNTF is found by the Department to have committed a violation of this chapter, the Department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a plan of correction indicating the following:
  - (a) How the deficiency will be corrected;
  - (b) The date upon which each deficiency will be corrected;
  - (c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
  - (d) How the corrective action will be monitored to ensure that the deficient practice does not recur.
- (4) Either failure to submit a plan of correction in a timely manner or a finding by the Department that the plan of correction is unacceptable shall subject the NRNTF's license to possible disciplinary action.
- (5) Any licensee or applicant for a license, aggrieved by a decision or action of the Department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §4-5-101, et seq.
- (6) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-4-1-.18 regarding petitions for reconsiderations and stays in that case.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206 through 68-11-209, and 68-11-213 and Executive Order 44 (February 23, 2007).

**Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed March 1, 2007; effective May 15, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

#### **0940-5-42-.04 ADMINISTRATION.**

- (1) The governing body shall ensure the following:
  - (a) The facility complies with all applicable federal, state and local laws, ordinances, rules, regulations and accreditation requirements.

(Rule 0940-5-42-.04, continued)

- (b) The facility is administered and operated in accordance with written policies and procedures.
- (c) There is general direction over the facility and policies established governing the operation of the facility and the welfare of the individuals served.
- (d) A responsible individual is designated for operation of the facility.
- (e) The licensed facility serves only persons whose placement will not cause the facility to violate its licensed status and capacity based on the facility's distinct licensure category, the facility's life safety occupancy classification, and the required staffing ratios.
- (f) A written policies and procedures manual is maintained. The manual shall include the following elements:
  - 1. A description of each facility service provided by the licensee. The description must include the hours of operation, and admission and discharge criteria.
  - 2. An organizational chart or a statement which clearly shows or describes the lines of authority between the governing body, the chief executive officer, and the staff.
  - 3. Policy and procedures which ensure that someone is delegated the authority to act in the absence of the individual responsible for the operation of the facility.
  - 4. A schedule of fees, if any, currently charged to the client for all services provided by the licensee. The schedule must identify all fees which are chargeable to clients and a copy of the schedule shall be provided to the client, or to a parent, guardian or responsible party during the admission process.
  - 5. A statement of client rights and a policy which establishes a definite procedure by which grievances presented by the client, his/her physician, relative (friends in some instances), staff or administrator may be handled.
  - 6. Policy and procedures which ensure the confidentiality of client information and which include the following provisions:
    - (i) The facility staff shall comply with applicable confidentiality laws and regulations;
    - (ii) The client shall not be required to make public statements which acknowledge gratitude to the licensee or for the licensee's facility services;
    - (iii) The client shall not be required to perform in public gatherings;
    - (iv) Identifiable photographs of the client shall not be used without the written and signed consent of the client or the client's guardian; and
    - (v) A medication administration policy and control procedures for facilities involved in the administration of medication to clients.

This policy and procedures must include a written notice of rights and responsibilities provided to each client at orientation.

(Rule 0940-5-42-.04, continued)

7. The plans and procedures to be followed in the event of fire evacuation, bomb threat and natural disaster emergencies evidenced by a record that the clients and staff have been informed of the procedures.
8. The plans and procedures to be followed in the event of an emergency involving client care which will provide for emergency CPR and initial care at the facility, emergency transportation of clients, emergency medical care, and staff coverage in such events.
9. A policy which prohibits clients from having any of the following responsibilities:
  - (i) Responsibility for the care of other clients;
  - (ii) Responsibility for the supervision of other clients unless on-duty/on-site staff are present; and
  - (iii) Responsibilities requiring access to confidential information.
10. Policy and procedures to be followed in the reporting and investigation of suspected or alleged abuse or neglect of clients, or other critical incidents. The procedures must include provisions for corrective action to be taken as a result of such reporting and investigation.
11. Policy and procedures which ensure that volunteers, if used by the facility, are in a supportive capacity, are under the supervision of appropriate designated staff members, and understand confidentiality and privacy of the client.
12. Policy and procedures for the purpose of admitting and assessing deaf and hard of hearing individuals which shall include a mechanism for providing sign language interpreters for all clients whose primary means of communication is through manual communication. Interpreters shall be qualified.
13. A policy regarding the use of human subjects in research, if the facility is involved or planning to be involved in such research, which includes procedures for the following:
  - (i) Identification of subjects, projects, and staff;
  - (ii) Provisions to protect the personal and civil rights of the subjects;
  - (iii) Obtaining informed consent of the subjects prior to research;
  - (iv) Assurance that all research projects are conducted under the direction and supervision of professional staff qualified by education and experience to conduct research;
  - (v) Emergency guidelines for problems that may develop during research activities;
  - (vi) Appointment of a facility representative to act as coordinator of the research activities; and
  - (vii) An identified individual and phone number for a client/guardian to call if there are any problems that develop during research activities.

(Rule 0940-5-42-.04, continued)

14. Monitoring procedures for multiple enrollment and cumulative time in all prior narcotic replacement treatment episodes with other narcotic treatment programs in Tennessee and participation in the central registries of adjoining states, if the programs are within 125 miles of the adjoining states' boundaries.
15. Pharmacotherapy guidelines for narcotic replacement treatment clients covering the program's own prescribing and review of prescriptions from other physicians which shall minimally include assurance that clients' prescriptions from outside physicians will be reported to the medical staff and reviewed by the program physician.
16. Evaluation criteria, clinical justification process, and ongoing review procedures will be in the form of an annual justification form and a six month update form, completed by the primary counselor, included in the client's chart detailing why a client is to remain in treatment as determined by multidisciplinary team evaluation and signed by the program physician or medical director of the program.
17. Procedures for providing non-narcotic replacement treatment detoxification services to opiate dependent clients who are no longer eligible for further narcotic replacement treatment services. Such services may be provided directly by the agency or indirectly through referrals based on written agreements with other service providers.
18. Procedures for medically supervised withdrawal in the event the patient becomes unable to pay for treatment, including an appropriate time frame over which the procedure would take place.
19. Policy and procedures which address the methods for managing disruptive behavior. If restrictive procedures are used to manage disruptive behaviors, written policies and procedures must govern their use and must minimally address the following:
  - (i) Any restrictive procedure shall be used by the facility only after all less-restrictive alternatives for dealing with the problem behavior have been systematically tried or considered and have been determined to be inappropriate or ineffective;
  - (ii) The client shall have given prior written consent to any restrictive measures taken with him/her by the staff;
  - (iii) The restrictive procedure(s) shall be documented in the Individual Treatment Plan, be justifiable as part of the plan, and meet all requirements that govern the development and review of the plan;
  - (iv) Only qualified personnel may use restrictive procedures and shall be adequately trained in their use; and
  - (v) The adaptive or desirable behavior shall be taught to the client in conjunction with the implementation of the restrictive procedures.
20. A policy which states physical holding shall be implemented in such a way as to minimize any physical harm to the client and may only be used when the client poses an immediate threat under the following conditions:

(Rule 0940-5-42-.04, continued)

- (i) The client poses an immediate danger to self or others; and/or
    - (ii) To prevent the client from causing substantial property damage.
  - 21. Hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work. Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical exams and referral services, at least five days per week. Any patient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, including Sundays and State and Federal holidays, not to exceed two (2) consecutive days. Facilities shall provide the SNA with at least two weeks notice prior to any change in program hours.
  - 22. A facility that intends to voluntarily close shall notify the SNA no later than thirty days prior to closure. In order to assure continuity of care, any facility which closes, either voluntarily or involuntarily, will comply with all directions received from the SNA regarding the orderly transfer of clients and their records.
  - 23. Each licensee shall clearly identify the governing body in its policies and procedures manual.
  - 24. A Diversion Control Plan shall be in place at each clinic. The Diversion Control Plan must contain, at a minimum, the following:
    - (i) The Diversion Control Plan shall apply to all clients receiving more than five (5) take-home medications.
    - (ii) It will include a random call back program with mandatory compliance. This call back must be in addition to the regular schedule of clinic visits.
    - (iii) Each client receiving take-home medications must be called back at a minimum of once per three (3) months.
    - (iv) Upon call back a client must report to the clinic within twenty-four (24) hours of notification, with all take-home medications. The quantity and integrity of packaging shall be verified. If take-home medications are liquid or any take-home dose shows evidence of tampering, one dose must be replaced and sent for analysis to verify strength and contents.
    - (v) The facility shall maintain individual callback results in the client record.
    - (vi) The facility must maintain a current log of all callbacks with the results of compliance.
- (2) Financial Management.
- (a) The licensee holding or receiving funds or property for the client as trustee or representative payee will adhere to all laws, state and federal, that govern his/her position and relationship to the client.
  - (b) The licensee must prohibit staff and proprietors from borrowing money from clients.
  - (c) The licensee must not take funds or property of the client for the facility's own use or gain.

(Rule 0940-5-42-.04, continued)

- (d) The governing body shall provide for the preparation of an annual budget and approve such budget. Copies of the current year's budget and expenditure records must be available upon request by the Department for examination and review by the Department.

(3) Personnel.

- (a) A personnel record for each staff member of a facility shall include an application for employment and/or resume and a record of any disciplinary action taken. A licensee shall maintain written records for each employee and each individual file shall include:
  - 1. Identifying information including name, current address, current telephone number, emergency contact person(s);
  - 2. A ten-year employment history or a complete employment history if the person has not worked ten years;
  - 3. Records of educational qualifications if applicable;
  - 4. Date of employment;
  - 5. The person's job description or statements of the person's duties and responsibilities;
  - 6. Documentation of training and orientation required by these rules;
  - 7. Any records relevant to the employee's performance; and
  - 8. Evidence that any professional license required as a condition of employment is current and in good standing.
- (b) Wage and salary information, time records, and authorization and record of leave, shall be maintained but may be kept in a separate location.
- (c) A job description shall be maintained which includes the employment requirements and the job responsibilities for each facility staff position.
- (d) A personnel record shall be maintained which verifies that each employee meets the respective employment requirements for the staff position held, including annual verification of basic skills and annual evaluation of personnel performance. This evaluation shall be in writing. There shall be documentation to verify that the employee has reviewed the evaluation and has had an opportunity to comment on it.
- (e) Training and development activities which are appropriate in assisting the staff in meeting the needs of the clients being served shall be provided for each staff member including STD/HIV education. The provision of such activities shall be evidenced by documentation in the facility's records.
- (f) Training and development activities which are appropriate in assisting volunteers (if volunteers are used by the facility) in implementing their assigned duties shall be provided for each volunteer. The provision of such activities shall be evidenced by documentation in the facility's records.

(Rule 0940-5-42-.04, continued)

- (g) Direct-services staff members shall be competent persons aged eighteen (18) years of age or older.
  - (h) All new employees, including volunteers, who have routine contact with clients shall have a current tuberculosis test prior to employment.
  - (i) Employees shall have a tuberculin skin test annually and at the time of exposure to active TB and three months after exposure.
  - (j) Employee records shall include date and type of tuberculin skin test used and date of tuberculin skin test results, date and results of chest x-ray, and any drug treatment for tuberculosis.
- (4) Staffing.
- (a) Program Director. The governing body of each facility shall designate in writing a program director who is responsible for the operation of the facility and overall compliance with federal, state and local laws and regulations regarding the operation of narcotic treatment programs, and for all employees including practitioners, agents, or other persons providing services at the facility. Facilities must notify the Department in writing within ten (10) calendar days whenever there is a change in program director.
  - (b) Medical Director. The governing body of each facility shall designate in writing a medical director to be responsible for the administration of all medical services, including compliance with all federal, state and local laws and regulations regarding the medical treatment of narcotic addiction. No physician may serve as medical director of more than one NTF without the prior written approval of the SNA. Facilities must notify the Department in writing within ten (10) calendar days whenever there is a change in medical director.
  - (c) Program Physician. Facilities are required to provide sufficient physician coverage to provide the medical treatment and oversight necessary to serve client needs. A program physician's responsibilities include, but are not limited to, performing medical history and physical exams, determination of diagnosis under current DSM criteria, determination of narcotic dependence, reviewing treatment plans, determining dosage and all changes in dosage, ordering take-home privileges, discussing cases with the treatment team and issuing any emergency or verbal orders relating to client care. At all times a facility is open and a physician is not present, a program physician must be available for consultation and emergency orders. Facilities must be able to document a referral agreement with a local hospital or health care facility.
  - (d) Physician's Assistants and Nurse Practitioners. Licensed physician's assistants and certified nurse practitioners may be employed by facilities and perform any functions permitted under Tennessee law.
  - (e) Nurses. Facilities shall insure that adequate nursing care is provided at all times the facility is in operation and that a nurse is present at all times medication is administered at the facility. Facilities that do not employ a registered nurse to supervise the nursing staff must ensure that licensed practical nurses adhere to written protocols and are properly supervised.
  - (f) Counselors. There must be sufficient group and individual counseling available to meet the needs of the client population. At a minimum, the following counseling schedule shall be followed:



(Rule 0940-5-42-.04, continued)

1. During the first ninety (90) days of treatment, counseling session(s) shall take place at least one time a week;
2. During the second ninety (90) days of treatment, counseling session(s) shall take place at least three (3) times per month;
3. During the third ninety (90) days of treatment, counseling session(s) shall take place at least two (2) times per month;
4. For subsequent ninety (90) day periods of treatment, counseling session(s) shall take place as needed or indicated in the client's treatment plan, but no less frequent than monthly as long as the client is compliant;
5. If the client experiences a relapse, his/her individualized treatment plan must document evidence of intensified services provided. Such evidence may include, but is not limited to, increase in individual or group counseling session(s) and/or a reduction in the client's take home privileges.

(5) Staff Qualifications.

- (a) Medical Director. All medical directors shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain their licenses in good standing and shall have the following experience and/or credentials:
  1. Three (3) years documented experience in the provision of services to persons who are addicted to alcohol or other drugs, including at least one (1) year of experience in the treatment of narcotic addiction with a narcotic drug; or
  2. Board eligibility in psychiatry and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or
  3. Certification as an addiction medicine specialist by the American Society of Addiction Medicine (ASAM).
- (b) Variance From Medical Director Qualifications. Facilities that are unable to secure the services of a medical director who meets the requirements of subparagraph (a) above may apply to the SNA for a variance. The SNA has the discretion to grant such a variance when there is a showing that:
  1. The facility has made good faith efforts to secure a qualified medical director, but has failed;
  2. The facility can secure the services of a licensed physician who is willing to serve as medical director and participate in the training plan;
  3. A training plan has been developed which is acceptable to the SNA and which consists of a combination of continuing education in addiction medicine and in-service training by a medical consultant who meets the qualifications specified in subparagraph (a) above; and,
  4. A medical consultant who meets the requirements of subparagraph (a) above will be available to oversee the training of the medical director and the delivery of medical services at the program requesting the variance.

(Rule 0940-5-42-.04, continued)

- (c) Program Physician. All program physicians must be licensed to practice medicine in Tennessee, must maintain their licenses in good standing and must have at least one (1) year of documented experience in the treatment of persons addicted to alcohol or other drugs.
- (d) Variance From Program Physician Qualifications. Facilities seeking to employ a program physician, in addition to the medical director, but are unable to secure the services of a program physician who meets the requirements of subparagraph (c) above may apply to the SNA for a variance. The SNA has the discretion to grant such a variance when there is a showing that:
  - 1. The facility has made good faith efforts to secure a qualified program physician, but has failed;
  - 2. The facility can secure the services of a licensed physician who is willing to serve as program physician and participate in the training plan;
  - 3. A training plan has been developed which is acceptable to the SNA and which consists of a combination of continuing education in addiction medicine and in-service training by the program's medical director; and
  - 4. The facility employs a qualified medical director who has the experience and credentials specified in subparagraph (a) above, has completed the training program specified in subparagraph (b) above or has completed the continuing education specified in subparagraph (e) below.
- (e) Current Medical Directors and Program Physicians. All physicians serving as medical director or program physician as of the effective date of these rules who do not meet the criteria specified above will be deemed qualified provided that they obtain 50 hours of continuing education in addiction medicine approved by the SNA within two years from the effective date of these rules. At least 25 hours of this continuing education must be obtained within one year from the effective date of these rules.
- (f) Nurses. All registered nurses and licensed practical nurses must be licensed to practice in Tennessee and must maintain their licenses in good standing.
- (g) Counselors. All counselors must be qualified by training, education and experience to provide addiction counseling services as required by these rules.
- (h) Program Directors. All program directors must have at least one year of supervisory or administrative experience in the field of substance abuse treatment.
- (i) Professional Practice. All professional staff, including but not limited to, physicians, pharmacists, physicians' assistants, nurses, and counselors may perform only those duties that are within the scope of their applicable professional practice acts and Tennessee licenses.
- (j) Staff Training and Orientation. Prior to working with clients, all staff who provide treatment and services must be oriented in accordance with these rules and must thereafter receive additional training in accordance with these rules. Orientation must include instruction in:
  - 1. The facility's written policies and procedures regarding its purpose and description; client rights, responsibilities, and complaints; confidentiality; and

(Rule 0940-5-42-.04, continued)

- other policies and procedures that are relevant to the employee's range of duties and responsibilities;
  - 2. The employee's assigned duties and responsibilities; and
  - 3. Reporting client progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services.
- (k) Additional training consisting of a minimum of eight (8) clock hours of training or instruction must be provided annually for each staff member who provides treatment or services to clients. Such training must be in subjects that relate to the employee's assigned duties and responsibilities, and in subjects about current clinical practice guidelines for narcotic treatment such as dosage, based on physician's clinical decision-making and individual client needs; drug screens; take-home medication practices; phases of treatment; treating abusers of multiple substances; narcotic treatment during pregnancy; HIV and other infectious diseases; co-morbid psychiatric conditions; and referring clients for primary care or other specialized services. Facilities shall maintain records documenting that each staff member has received the required annual training.
- (l) Employee Drug Screening. Facilities shall establish and implement written policies and procedures for pre-employment and ongoing random drug screening of all facility employees. Each sample collected must be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by the SNA.
- (m) Staff Ratios and Responsibilities. The facility shall have sufficient types and numbers of staff to provide the treatment and services required by all applicable state and federal laws and regulations and as outlined in its program description and these rules.
- (n) A minimum of one (1) on-duty staff member trained in CPR, Heimlich Maneuver, and First Aid shall be maintained.
- (6) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:
  - (a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;
  - (b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and
  - (c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-222, and 71-6-121 and Executive Order 44 (February 23, 2007). **Administrative**

**History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18,

(Rule 0940-5-42-.04, continued)

*2003; effective May 4, 2003. Amendment filed April 30, 2003; effective July 14, 2003. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

**0940-5-42-.05 ADMISSIONS, DISCHARGES AND TRANSFERS.**

- (1) The facility shall maintain written policies and procedures governing the intake and assessment process and specify the following:
  - (a) The information to be obtained on all applicants or referrals for admission;
  - (b) The procedures for accepting referrals from outside agencies or organizations;
  - (c) The records to be kept on all applicants;
  - (d) Any prospective client data to be recorded during the intake process; and
  - (e) The procedures to be followed when an applicant or a referral is found ineligible or admission.
- (2) Screening, Admission, and Orientation of Clients.
  - (a) A facility may only admit and retain clients whose known needs can be met by the facility in accordance with its program purpose and description and applicable federal and state laws and regulations. Written policies and procedures for client referral, intake, assessment, and admission must be established and implemented and must include the following provisions or requirements:
    1. Screening. All applicants for admission must be initially screened by facility staff to determine eligibility for admission. No applicant may be processed for admission until it has been verified that he or she meets all applicable criteria, and that the sources and methods of verification have been recorded in the applicant's case folder. The screening process must include:
      - (i) Verification, to the extent possible, of an applicant's identity, including name, address, date of birth and other identifying data;
      - (ii) Drug history and current status, including determination and substantiation, to the extent possible, of the duration of substance dependence, determination by medical examination performed by a program physician of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group, and determination of current DSM diagnosis;
      - (iii) Medical history, including HIV status, pregnancy, current medications (prescription and nonprescription), and active medical problems;
      - (iv) Psychiatric history and current mental status exam;
      - (v) Physical assessment and laboratory tests, including drug screens and HIV status (if the applicant consents to be tested), pregnancy, STD, and Mantoux TB tests;
      - (vi) If an applicant has previously been discharged from treatment at another methadone clinic or program, the admitting facility must initiate an

(Rule 0940-5-42-.05, continued)

- investigation into the applicant's prior treatment history, inquiring of the last program attended the reasons for discharge from treatment;
- (vii) Determination if the applicant needs special services, such as treatment for alcoholism or psychiatric services, and determination that the facility is capable of addressing these needs either directly or through referral;
  - (viii) Explanation of treatment options, detoxification rights, and clinic charges, including the fee agreement, signed by the applicant;
  - (ix) If an applicant is 18 years of age or older, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of one year; and
  - (x) If an applicant is under 18 years of age, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years.
2. Assessment. Each client admitted to the facility must be evaluated by the medical director or program physician and clinical staff who have been determined to be qualified by education, training, and experience to perform or coordinate the provision of such assessments. The purpose of such assessments shall be to determine whether narcotic substitution, short-term detoxification, long-term detoxification, or drug free treatment will be the most appropriate treatment modality for the client. The evaluation must include an assessment of the client's needs for other services including treatment, educational and vocational.
3. Admission.
- (i) Consent. Except as otherwise authorized by law, no person may be admitted for treatment without written authorization from the client and, if applicable, parent, guardian or responsible party. The following information must be explained by a trained staff person to the client and other consenters, and documented in the client file:
    - (I) The program's services and treatment;
    - (II) The specific condition that will be treated;
    - (III) The expected charges for services including any charges that might be billed separately to the client or other parties; and,
    - (IV) The facility's rules regarding client conduct and responsibilities.
  - (ii) Admission Clearance. No person may be admitted unless the facility conducts an inquiry with the Central Registry in accordance with rule 0940-5-42-.05 (4).
  - (iii) Orientation. The facility shall provide orientation to clients within 24 hours of admission for treatment. Orientation must be done by a staff person who has been determined to be qualified by education, training, and experience to perform the task. Facilities shall ensure that each client signs a statement confirming that the following information has been explained to the client:

(Rule 0940-5-42-.05, continued)

- (I) The expected benefits of the treatment that the client is expected to receive;
    - (II) The client's responsibilities for adhering to the treatment regimen and the consequences of non-adherence;
    - (III) An explanation of individualized treatment planning;
    - (IV) The identification of the staff person who is expected to provide treatment or coordinate the treatment;
    - (V) Facility rules including requirements for conduct and the consequences of infractions;
    - (VI) Client's rights, responsibilities, and complaint procedures;
    - (VII) Drug screening policies and procedures; and
    - (VIII) HIV information.
  - (b) Drug dependent pregnant females must be given priority for admission and services when a facility has a waiting list for admissions and it is determined that the health of the mother and/or unborn child is more endangered than is the health of other clients waiting services. Pregnancy tests for females must be conducted at admission and at least annually thereafter, unless otherwise indicated.
  - (c) No facility may provide a bounty, free services, medication or other reward for referral of potential clients to the clinic.
  - (d) Non-Admissions. The facility shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs must identify the reasons why the persons were not admitted and what referrals were made for them by the facility.
- (3) Discharge and Aftercare Plans. A facility must complete an individualized discharge and aftercare plan for clients who complete their course of treatment. This plan must be developed prior to discharge and must be completed within seven days of discharge by the person who has primary responsibility for coordinating or providing for the care of the client. It must include a final assessment of the client's status at the time of discharge and a description of aftercare plans for the client. The client must participate in discharge and aftercare planning and, if applicable, parents or guardian, or responsible persons should participate.
- (4) Central Registry.
- (a) To prevent simultaneous enrollment of a client in more than one facility, all facilities shall participate in a central registry approved by the Department. Clients must be informed of the facility's participation in the central registry and prior to initiating a central registry inquiry, the facility must obtain the client's signed consent. Within seventy-two (72) hours of admission, the facility shall initiate a clearance inquiry by submitting to the approved central registry the name, date of birth, anticipated date of admission or discharge and any other relevant information required for the clearance procedure. No person shall be admitted to a facility who is reported by the central registry to be participating in another such facility, or in the event a dual enrollment is found, the client must be discharged from one facility in order to continue enrollment at

(Rule 0940-5-42-.05, continued)

another facility. Reports received by the central registry shall be treated as confidential and shall not be released except to a licensed facility, or as required by law. Information made available by the central registry to facilities shall also be treated as confidential.

- (b) To prevent simultaneous enrollment of persons in different facilities located in different states, if a facility operates within 125 miles of any adjoining state and that state also has a central registry, the facility shall, at the direction of the SNA, also participate in the central registry of the adjoining state.
- (5) The facility shall provide services, as available, to clients to address their needs as indicated on the assessment/ history in the areas of social/ family/ peer, employment/ education/ financial, emotional/ psychological health, physical health, legal, and community living skills/housing. Such services may be provided directly by the agency or indirectly by referral to other service providers. Referral agreements with frequently used providers must be documented. The provision of such services to individual clients must be documented in the client record. The facility shall ensure that clients are instructed in the proper storage and security of take-home medications after they leave the facility.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, and 68-11-209 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

#### **0940-5-42-.06 BASIC SERVICES.**

- (1) Quality of Care. The Narcotic Treatment facility will develop and implement a plan for continuous quality improvement. At a minimum, the plan shall include:
  - (a) Structured assessment of the program which addresses program management, staffing, policies and procedures and general operations.
  - (b) A service delivery assessment which at a minimum shall evaluate appropriateness of the treatment plan and services delivered, completeness of documentation in clients' records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out-of-program services, and availability of services and medications for other conditions (e.g. prenatal, T.B., HIV).
  - (c) An assessment of utilization and cost effectiveness of the services delivered which shall examine treatment slot utilization and cost per slot, staff to client ratio and cost per counseling session and other support services.
  - (d) An assessment of medication related issues including take-home procedure, security, inventory and dosage issues.
  - (e) Such process shall serve to continuously monitor the program's compliance with the requirements set forth in these rules. Responsibility for administering and coordinating the quality improvement process must be delegated to a staff person who has been determined to be qualified by education, training, and experience to perform such tasks. The medical director shall be actively involved in the process.
  - (f) Programs shall participate in additional quality improvement outcome studies as directed by the Department or SNA.

(Rule 0940-5-42-.06, continued)

- (2) Performance Outcome. The Narcotic Treatment Facility shall monitor performance outcome. The following performance indicators may be used to evaluate the impact of the program on clients and the community:
  - (a) Client receipt of needed program or out-of-program services.
  - (b) Client satisfaction.
  - (c) Client employment status.
  - (d) Improvement in medical conditions.
  - (e) Drop-out rates.
  - (f) Recidivism rates.
  - (g) Alcohol use.
  - (h) Criminal arrests.
  - (i) Illicit drug use, as indicated by drug screens.
  - (j) Improvement in social and living standards.
- (3) Staff Training. The Narcotic Treatment Facility shall promote, utilize and provide staff training on current clinical practice guidelines for narcotic replacement treatment. The following areas shall receive emphasis during training:
  - (a) Dosage.
  - (b) Counseling.
  - (c) Urinalysis.
  - (d) Phases of treatment.
  - (e) Treating multiple substance abuse.
  - (f) Narcotic treatment during diseases.
  - (g) HIV and other infectious diseases.
  - (h) Co-morbid psychiatric conditions.
  - (i) FDA-approved drugs for the treatment of opiate addiction, including methadone and LAAM.
- (4) Community Relations. The Narcotic Treatment Facility shall develop procedures for community relations to include the following:
  - (a) Identify community leaders (representatives within the area in which the clinic is situated as well as in the districts served) and establish interpersonal contact, liaison, education or proactive association in an advisory group with elected officials, health,



(Rule 0940-5-42-.06, continued)

substance and human service directors, business leaders, law enforcement, religious and spiritual leaders and community grass roots organizations.

- (b) Develop a community relations plan specific to the configuration and needs of the facility within the community to include the following:
    - 1. Liaison with community representatives.
    - 2. Define the goals and procedures of the community relations plan.
    - 3. Provide a mechanism to hear community concerns about the narcotic treatment facility's presence and operations in the community.
    - 4. Develop policies and procedures to resolve community issues and problems to insure that program operations do not adversely affect community life.
    - 5. Document all community relations efforts, community contacts and resolutions, and evaluate these efforts and contacts over time.
  - (c) A facility shall be responsible for assuring that its clients do not cause unnecessary disruption to the community by loitering in the vicinity or acting in a manner that would constitute disorderly conduct or harassment. Clients who consistently cause disruption to the community or to the facility should be discharged from the program.
  - (d) Each facility shall provide the Department, when requested, with a specific plan describing the efforts it will make to avoid disruption of the community by its clients and the actions it will take to assure responsiveness to community needs. The Department may require that such plan include the formation of a committee to consist of representative members of the community. Such committee shall meet on a regular basis.
- (5) Individual Treatment Planning. A facility must develop an individual treatment plan for each client within thirty (30) days of admission. Clients must be involved in the development of their treatment plans. Treatment plans must document a consistent pattern of substance abuse treatment services and medical care appropriate to individual client needs.
- (a) Medical care, including referral for necessary medical service, and evaluation and follow-up of client complaints must be compatible with current and accepted standards of medical practice. All clients must receive a medical examination at least annually. All other medical procedures performed at the time of admission must be reviewed by the medical staff on an annual basis, and all clinically indicated tests and procedures must be repeated. The medical director or program physician shall record the results of this annual medical examination and review of client medical records in each client's record.
  - (b) In recognition of the varied medical needs of clients, the case history and treatment plan must be reviewed at least every 90 days for clients in treatment less than a year and at least annually for clients in treatment more than a year. This review will be conducted by the medical director or program physician along with the primary counselor and other appropriate members of the treatment team for general quality controls and evaluation of the appropriateness of continuing the form of treatment on an ongoing basis. This review must also include an assessment of the current dosage and schedule and the rehabilitative progress of the individual, as part of a determination of whether additional medical services are indicated. If this review results

(Rule 0940-5-42-.06, continued)

- in a determination that additional or different medical services are indicated, the facility must ensure that such services are made available to the client.
- (c) When the program physician prescribes other controlled substances to clients in the facility, the facility shall ensure that such prescription is in accord with all applicable statutes and regulations and with current and accepted standards of medical practice. Such prescriptions shall not be issued to any client unless the physician first sees the client and assesses the client's potential for abuse of such medications.
  - (d) As part of the rehabilitative services provided by the facility, each client must be provided with individual and group counseling appropriate to his/her needs. The frequency and duration of counseling provided to clients must be determined by appropriate program staff and be consistent with the treatment plan. Treatment plans must indicate a specific level of counseling services needed by the client as part of the rehabilitative process.
  - (e) All clients shall receive HIV risk reduction education appropriate to their needs.
  - (f) When appropriate, each client must be enrolled in an education program, or be engaged in a vocational activity (vocational evaluation, education or skill training) or make documented efforts to seek gainful employment. Deviations from compliance with these requirements must be explained in the client's record. Each facility shall take steps to ensure that a comprehensive range of rehabilitative services, including vocational, educational, legal, mental health, alcoholism and social services are made available to the clients who demonstrate a need for such services. The facility can fulfill this responsibility by providing support services directly or by appropriate referral. Support services recommended and utilized must be documented in the client record.
  - (g) All facilities will develop and implement policies for matching client needs to treatment. These policies may include treatment phasing in which the intensity of medical, counseling and rehabilitative services provided to a client varies depending upon the client's phase of treatment. Phases of treatment may include intensive stabilization for new clients and those in need of acute care, graduated rehabilitation phases, and for long-term stable clients, a medical maintenance or methadone-tapering phase.
  - (h) Each client's individualized treatment plan must include the counseling needs, including both group and individualized counseling sessions as indicated by evaluation of the client's length of time in the program, drug screening results, progress notes, and social environment. The treatment plan must be reviewed at least every six (6) months.
- (6) Infection Control. A facility must develop policies and procedures to be followed for infection control, including:
- (a) Reporting all suspected or diagnosed cases of infectious disease including tuberculosis, AIDS, and sexually transmitted disease (STD) promptly to the regional health department in accordance with 42 C.F.R., Part 2 and T.C.A. §§68-10-101, 68-9-201 and 68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health;
  - (b) Management of clients who are infected with Hepatitis B or C Virus, HIV/AIDS or other STD;
  - (c) Nondiscrimination of employees and clients regarding their HIV/AIDS status;

(Rule 0940-5-42-.06, continued)

- (d) Use of standard precautions for prevention of transmission of HIV/AIDS, Hepatitis B or C Virus, and other blood borne pathogens;
  - (e) Infectious disease testing will be made on a voluntary basis for any client who requests it, and be documented in appropriate records;
  - (f) Assurance that a client's HIV, other STD, and tuberculosis status will be kept confidential in accordance with "Confidentiality of Alcohol and Drug Abuse Patient Records" (42 C.F.R., Part 2);
  - (g) Documentation on the establishment of linkages between the facility and the local health department to ensure clients receive appropriate medical care relative to their infection and/or exposure to TB, Hepatitis B or C, and STD (including HIV), i.e., establish contact between the health department and the facility to communicate appropriate information to assure that the client receives appropriate care;
  - (h) Informed consent of clients before screening and treatment; and
  - (i) Conducting case management activities to ensure that individuals receive appropriate treatment services for HIV/AIDS, Hepatitis B or C Virus and other sexually transmitted diseases, and tuberculosis.
- (7) Client Records.
- (a) Facilities must organize and coordinate client records in a manner which demonstrates that all pertinent client information is accessible to all appropriate staff and to the Department. The client Central Registry I.D. number must be shown on each page of the client's record. Each client record must contain, at a minimum, the following:
    - 1. The name of the client.
    - 2. The address of the client.
    - 3. The current telephone number of the client.
    - 4. The sex of the client.
    - 5. The date of the client's birth.
    - 6. The date of the client's admission to the program.
    - 7. The source of the client's referral to the facility.
    - 8. The name, address, and telephone number of an emergency contact person.
    - 9. If the facility charges fees for its services, a written fee agreement dated and signed by the client (or the client's legal representative) prior to provision of any services. This agreement shall include at least the following information:
      - (i) The fee or fees to be paid by the client;
      - (ii) The services covered by such fees;

(Rule 0940-5-42-.06, continued)

- (iii) Any additional charges for services not covered by the basic service fee; and
    - (iv) Procedures for medically supervised withdrawal in the event the patient becomes unable to pay for treatment.
  - 10. Appropriate signed and dated informed consent and authorization forms for the release or obtainment of information about the client.
  - 11. Documentation that the client or someone acting on behalf of the client has been informed of the client's rights and responsibilities and of the facility's general rules affecting the client.
  - 12. Documentation of Central Registry clearance as required in paragraph 0940-5-42-.05 (4) of these rules.
- (b) Records shall be retained for a minimum of five (5) years even if a facility discontinues operations.
- (c) The Department must be notified in advance of a facility's closing.
- (d) Upon the closing of any facility, a person of authority representing the facility may request final storage or disposition of the facility's records by the Department.
- (8) Drug Screens. The facility shall develop and implement written policies and procedures for random drug screens. These policies and procedures will be for the purposes of assessing the client's abuse of drugs and making decisions about the client's treatment. These policies and procedures must include the following provisions:
  - (a) Urine drug screens must be conducted on a random basis weekly for new clients during the first thirty days of treatment and at least monthly thereafter. However, clients on a monthly schedule whose drug screen reports indicate drug abuse will be returned to a weekly schedule for at least two weeks, or longer if clinically indicated.
  - (b) Each sample collected must be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, THC and other drugs as indicated by individual client use patterns or that are heavily used in the locale of the client or as directed by the SNA.
  - (c) Facilities shall develop policies to ensure that urine collected from clients is unadulterated. Such policies may include random direct observation which shall be conducted professionally, ethically, and in a manner which respects clients' privacy.
- (9) Narcotic Drugs. Facilities shall develop and implement written policies and procedures for prescription and administration of narcotic drugs and their security. These policies and procedures must include the following:
  - (a) Administration.
    - 1. A program physician shall determine the client's initial and subsequent dose and schedule. If the physician did not perform the medical assessment required in these rules, the physician must consult with the person who performed the assessment before determining the client's initial dose and schedule. The physician shall communicate the initial and subsequent dose and schedule to the pharmacy or the person supervising medication. The physician may assign such

(Rule 0940-5-42-.06, continued)

- dose and schedule by verbal order, however, all such orders must be confirmed in writing by the physician within 72 hours.
2. Proper dose should be based on the clinical judgment of the program physician who has examined the client and who has considered all available relevant information, including, but not limited to, drug screens, quantitative methadone levels, client interview, and specific circumstances pertaining to the individual client.
  3. The initial dose of methadone may not exceed 30 milligrams. Additional dosage may be given in the first day where the physician documents that 30 milligrams does not suppress withdrawal symptoms. Only in extraordinary circumstances may the total dose for the first day exceed 40 milligrams. A transferring client may receive an initial dosage of no more than the last daily dosage authorized at the former facility unless in the clinical judgment of the medical director, there are extenuating circumstances documented in the record which justify an initial dosage that is greater than the last daily dosage authorized at the former facility.
  4. Clients are stabilized on methadone when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the client comfortable for at least 24 hours with no need to resort to illicit opiates to satisfy opiate cravings.
  5. The dose must be administered by a professional authorized by law to do so. No methadone may be administered unless the applicant has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the records. In that case, intake procedures must be completed on the next working day. No take-home medication may be given in such an emergency.
  6. No dose of methadone in excess of 120 milligrams may be ordered or administered without the prior approval of the SNA.
- (b) Any narcotic drug prescribed and administered shall be documented on an individual medication administration record that is filed with the individual treatment plan. The record must include:
1. Name of medication;
  2. Date prescribed;
  3. Dosage;
  4. Frequency of administration;
  5. Route of administration;
  6. Date and time administered; and
  7. Documentation of staff administering medication or supervising self-administration.
- (c) Take-home doses of methadone and LAAM shall be handled in accordance with applicable rules of the Substance Abuse and Mental Health Administration or other

(Rule 0940-5-42-.06, continued)

applicable federal agency. All requests for take home exceptions must be reviewed and approved by the SNA and any other applicable federal agency.

- (d) Adverse drug reactions and errors must be reported to a program physician immediately and corrective action initiated. The adverse reaction or error must be recorded in the drug administration record, the nurse progress notes and the individual treatment plan, and all persons who are authorized to administer medication or supervise self-medication must be alerted.
- (e) All medications must be stored in a locked safe when not being administered or self-administered.
- (f) Medication orders and dosage changes must be written or printed on a form which clearly displays the physician's signature. Dosage dispensed, prepared or received must be recorded and accounted for by written or printed notation in a manner which achieves a perpetual and accurate inventory at all times. Every dose must be recorded in the client's individual medication record at the time the dose is dispensed or administered. If initials are used, the full signature and credentials of the qualified person administering or dispensing must appear at the end of each page of the medication sheet. The perpetual inventory must be totaled and recorded in milligrams daily. Where computer-based recording is utilized, the facility shall show that hard-copy records are maintained for inspection.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-209, 68-11-222, 68-11-305, and 68-11-308 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

**0940-5-42-.07 RESERVED.**

**0940-5-42-.08 BUILDING STANDARDS.**

- (1) The non-residential narcotic treatment facility must be constructed, arranged, and maintained to ensure the safety of the clients.
- (2) The condition of the physical plant and the overall non-residential narcotic treatment facility environment must be developed and maintained in such a manner that the safety and well-being of clients are assured.
- (3) When construction is planned by any facility for any building, additions to an existing building or substantial alterations to an existing building, two (2) sets of plans and specifications shall be submitted to the department to be approved. For the purpose of life safety, non-residential narcotic treatment facilities are required to meet business occupancies and all new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), and the National Electrical Code, as adopted by the Board for Licensing Health Care Facilities. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.).
- (4) Flammable and combustible liquids such as gasoline, cleaning fluids, kerosene, turpentine etc., shall be stored in safety containers and stored at least 16 feet from the building or stored in a U.L. approved/listed cabinet and ventilated as prescribed by code requirement or manufacturers' recommendation.
- (5) Mechanical

(Rule 0940-5-42-.08, continued)

- (a) All units having a total of 2,000 cubic feet per minute (CFM) or greater in a zone shall shut down when the fire alarm panel is activated.
- (6) Electrical
  - (a) The electrical system, components, equipment and appliances shall be kept in good repair at all times.
  - (b) Knob and Tube wiring is prohibited.
  - (c) Electrical cords shall not have splices.
  - (d) Electric circuit breaker panel boxes shall not have open slots exposing wiring.
  - (e) Circuit breakers shall be properly labeled.
  - (f) In all new facilities or renovations to existing electrical systems, the installation must be approved by an inspector or agency authorized by the State Fire Marshall.
  - (g) The electrical system shall not be overloaded.
  - (h) Ground-Fault Circuit Interrupters (GFCI) are required in all wet areas, such as kitchens, laundries, janitor closets, bath and toilet rooms, etc. and within six (6) feet of any laboratory.
- (7) Fire Alarm
  - (a) Manual pull stations shall be installed in paths of travel to exits and by each required exit.
  - (b) All alarm devices shall be connected to the fire alarm panel.
  - (c) The fire alarm panel shall have auxiliary power such as batteries or generators.
  - (d) All sprinkler systems are to be electrically supervised.
  - (e) Structures with atriums, vertical openings or monumental stairs open to another floor must have their fire alarm system automatically transmit an alarm to the municipal fire department or to an agency acceptable to this department with equipment which meets NFPA signaling and standard building codes. Fire protection systems and smoke evacuation systems must be on emergency power.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed June 21, 2007; effective September 4, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

**0940-5-42-.09 LIFE SAFETY.**

- (1) Any non-residential narcotic treatment facility which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(Rule 0940-5-42-.09, continued)

- (2) The non-residential narcotic treatment facility shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the department within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Records which document and evaluate these incidents must be maintained for at least three (3) years.
- (3) The non-residential narcotic treatment facility shall have a written emergency plan to document instructions to staff, upon employment, and clients, upon enrollment, in fire evacuation procedures. The plan shall include actions to be taken in inclement weather and internal and external emergencies. Evacuation plans shall be posted in prominent areas such as reception areas, near door in class rooms, etc. and shall designate meeting places outside the building in event of emergencies.
- (4) Corridor doors shall not have louvers.
- (5) Battery powered emergency lighting shall be installed in corridors, common areas and in stair ways.
- (6) Corridors shall be lighted at all times, to a minimum of one foot candle.
- (7) Corridors and exit doors shall be kept clear of equipment, furniture and other obstacles at all times. There shall be a clear passage at all times from the exit doors to a safe area.
- (8) Corridors in multi-storied buildings shall have two exits remote from each other. At least one exit shall be directly to the outside.
- (9) Storage beneath any stair is prohibited.
- (10) Combustible finishes and furnishings shall not be used.
- (11) Open flame and portable space heaters shall not be permitted in the facility. Cooking appliances other than microwave ovens shall not be allowed in the facility.
- (12) All heaters shall be guarded and spaced to prevent ignition of combustible material and accidental burns. The guard shall not have a surface temperature greater than 120°F.
- (13) Fireplaces and/or fireplace inserts may be used only if provided with guards or screens which are secured in place. Fireplaces and chimneys shall be inspected and cleaned annually and verified documentation shall be maintained.
- (14) All electrical equipment shall be maintained in good repair and in safe operating condition.
- (15) Electrical cords shall not be run under rugs or carpets.
- (16) The electrical systems shall not be overloaded. Power strips must be equipped with circuit breakers. Extension cords shall not be used.
- (17) Fire extinguishers, complying with NFPA 10, shall be provided and mounted to comply with NFPA 10. An extinguisher in the kitchen area shall be a minimum of 2-A:10 B:C and an extinguisher with a rating of 20-A shall be adjacent to every hazardous area. The minimum travel distance shall not exceed fifty (50) feet between the extinguishers.



(Rule 0940-5-42-.09, continued)

- (18) Smoking and smoking materials shall be permitted only in designated areas. Ashtrays must be provided wherever smoking is permitted. The facility shall have written policies and procedures for smoking within the facility which shall designate a room or rooms to be used exclusively for clients who smoke. The designated smoking room or rooms shall not be the dining room or activity room.
- (19) Trash and other combustible waste shall not be allowed to accumulate within and around the facility and shall be stored in appropriate containers with tight-fitting lids. Trash containers shall be UL approved.
- (20) All safety equipment shall be maintained in good repair and in a safe operating condition.
- (21) Janitorial supplies shall not be stored in the kitchen, food storage area, dining area or client accessible areas.
- (22) Emergency telephone numbers must be posted near a telephone accessible to the clients.

(Rule 0940-5-42-.09, continued)

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed June 21, 2007; effective September 4, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

**0940-5-42-.10 INFECTIOUS AND HAZARDOUS WASTE.**

- (1) Each facility must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.
- (2) The following waste shall be considered to be infectious waste:
  - (a) Waste contaminated by clients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals";
  - (b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures;
  - (c) Waste human blood and blood products such as serum, plasma, and other blood components;
  - (d) All discarded sharps (e.g., hypodermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) used in client care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories; and,
  - (e) Other waste determined to be infectious by the facility in its written policy.
- (3) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.
- (4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.
  - (a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;
  - (b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;
  - (c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste; and

(Rule 0940-5-42-.10, continued)

- (d) Opaque packaging must be used for pathological waste.
- (5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.
- (6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.
- (7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:
  - (a) Isolate the area from the public and all except essential personnel;
  - (b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of this section; and
  - (c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure must specify how this will be done.
- (8) Except as provided otherwise in this section, a facility must treat or dispose of infectious waste by one or more of the methods specified in this paragraph.
  - (a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device is rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious, unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation. Such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.
  - (b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.
  - (c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(Rule 0940-5-42-.10, continued)

- (9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is in Tennessee, the facility must ensure that it has all necessary state and local approvals, and such approvals shall be available for review. If the off-site location is in another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.
- (10) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material and shall be kept on elevated platforms.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

#### **0940-5-42-.11 RECORDS AND REPORTS.**

- (1) Reporting. The facility shall submit the following information to the Department:
  - (a) All reports, forms and correspondence submitted to the FDA, DEA, any other applicable federal agencies or required accreditation organizations.
  - (b) Written notification of the administration of greater than one hundred (100) milligrams of methadone to a client requires written notification within ten (10) working days, signed by the program physician, which details clinical justification for exceeding one hundred (100) milligrams.
  - (c) Such reports and information which may be required by the Department to conduct evaluations of narcotic replacement treatment effectiveness or monitor service delivery.
- (2) The NRNTF shall report each case of communicable disease to the local county health officer in the manner provided by T.C.A. §68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health. Repeated failure to report communicable diseases shall be cause for revocation of a facility license.
- (3) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.
  - (a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:
    1. medication errors;

(Rule 0940-5-42-.11, continued)

2. aspiration in a non-intubated patient related to conscious/moderate sedation;
3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;
4. volume overload leading to pulmonary edema;
5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;
6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;
7. burns of a second or third degree;
8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;
9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:
  - (i) procedure related injury requiring repair or removal of an organ;
  - (ii) hemorrhage;
  - (iii) displacement, migration or breakage of an implant, device, graft or drain;
  - (iv) post operative wound infection following clean or clean/contaminated case;
  - (v) any unexpected operation or reoperation related to the primary procedure;
  - (vi) hysterectomy in a pregnant woman;
  - (vii) ruptured uterus;
  - (viii) circumcision;
  - (ix) incorrect procedure or incorrect treatment that is invasive;
  - (x) wrong patient/wrong site surgical procedure;
  - (xi) unintentionally retained foreign body;
  - (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;
  - (xiii) criminal acts;
  - (xiv) suicide or attempted suicide;
  - (xv) elopement from the facility;

(Rule 0940-5-42-.11, continued)

- (xvi) infant abduction, or infant discharged to the wrong family;
  - (xvii) adult abduction;
  - (xviii) rape;
  - (xix) patient altercation;
  - (xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;
  - (xxi) restraint related incidents; or
  - (xxii) poisoning occurring within the facility.
- (b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:
- 1. strike by the staff at the facility;
  - 2. external disaster impacting the facility;
  - 3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and
  - 4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.
- (c) For health services provided in a “home” setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.
- (d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department’s approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.
- (e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report,

(Rule 0940-5-42-.11, continued)

then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

- (f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.
- (g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.
- (h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.
- (i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.
- (j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.
- (k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.
- (l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(Rule 0940-5-42-.11, continued)

- (4) The NRNTF shall retain legible copies of the following records and reports for thirty-six months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them. Each client must be fully informed of the availability of these reports to the public, of their location within the facility, and given an opportunity to inspect the file before entering into any monetary agreement with the facility:
  - (a) Local fire safety inspections;
  - (b) Local building code inspections, if any;
  - (c) Fire Marshall reports;
  - (d) Department licensure and fire safety inspections and surveys;
  - (e) Federal government surveys and inspections, if any;
  - (f) Orders of the Commissioner or Board, if any;
  - (g) Comptroller of the Treasury's audit reports and findings, if any; and
  - (h) Maintenance records of all safety equipment.
- (5) Inspections.
  - (a) The Department is authorized to conduct on-site inspections of any facility to verify compliance with these rules and all relevant laws or regulations. A facility shall permit any authorized Department representative to enter upon and inspect any and all facility premises which, for the purposes of these rules, shall include access to all parts of the facility, staff, persons in care, and documents pertinent to initial and continued licensure. Failure to permit entry and inspection is a violation of this rule and may result in the denial of any license applied for or the suspension or revocation of a license.
  - (b) If, as a result of an inspection, violations of these rules are identified, the Department may issue a written inspection report that identifies the rules violated and requires the facility to submit a written plan of correction that states what the program will do to correct each of the violations identified. The Department will provide written inspection reports to the facility within 30 days after the on-site inspection, unless there is a determination by the SNA that the complexity of the issues or other extenuating circumstances require an extension of this time period. The facility may offer any explanation or dispute the findings of violations in the written plan of correction so long as an acceptable plan of correction is submitted within 30 days of receipt of the inspection report. Failure to submit an acceptable plan of correction may constitute cause for the Department to deny a license or suspend or revoke a license. Nothing in this paragraph will be interpreted to mean that facilities must be afforded an opportunity to correct all violations. Upon the discovery of any violation of these rules, the Department may proceed to suspend or revoke a facility's license in accordance with these rules. In determining the appropriate response to rule violations, the Department will consider whether the violations can be corrected, the facility's history of compliance, the nature and seriousness of the violations, the impact of the violations on the safety and welfare of the facility's clients and the surrounding community and any other relevant circumstances.



(Rule 0940-5-42-.11, continued)

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed April 11, 2003; effective June 25, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

**0940-5-42-.12 CLIENTS RIGHTS.**

- (1) Confidential Records.
  - (a) All applications, certificates, records, reports and all legal documents, petitions and records made or information received pursuant to treatment in a NRNTF directly or indirectly identifying a client shall be kept confidential and shall not be disclosed by any person except the individual identified; and
  - (b) As a court may direct upon its determination that disclosure is necessary for the conduct of proceedings before it and that failure to make such disclosure would be contrary to the public interest or detrimental to either party to the proceedings, consistent with the provisions of 42 C.F.R. Part 2.
- (2) Nothing in this rule shall prohibit disclosure, upon proper inquiry, of information as to the current medical condition of a client to any members of the family of a client or to his relatives or friends providing that conditions of 42 C.F.R. Part 2 have been met.
- (3) Clients shall not be abused or neglected.
- (4) Facilities shall develop and implement written policies and procedures regarding the rights and responsibilities of clients, and the handling and resolution of complaints.
- (5) Other client rights include:
  - (a) Right to a humane treatment environment that affords reasonable protection from harm, exploitation, and coercion;
  - (b) Right to be free from physical and verbal abuse;
  - (c) Right to be informed about the individualized plan of treatment and to participate in the planning, as able;
  - (d) Right to be promptly and fully informed of any changes in the plan of treatment;
  - (e) Right to accept or refuse treatment;
  - (f) Right to confidentiality of client records;
  - (g) Right to be informed of the facility's complaint policy and procedures and the right to submit complaints without fear of discrimination or retaliation and to have them investigated by the program within a reasonable period of time;
  - (h) Right to receive a written notice of the address and telephone number of the state licensing authority, i.e. the Department; and
  - (i) Right to obtain a copy of the facility's most recent completed report of licensing inspection from the facility upon written request. The facility is not required to release a

(Rule 0940-5-42-.12, continued)

report until the facility has had the opportunity to file a written plan of correction for the violations as provided for in these rules.

- (6) The written policies and procedures shall include provisions for clients and others to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-209, 68-11-302, and 68-11-304 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

**0940-5-42-.13 REPEALED.**

**Authority:** T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Repeal filed April 30, 2003; effective July 14, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.

**0940-5-42-.14 DISASTER PREPAREDNESS.**

- (1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans, for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans shall be readily available at all times in the telephone operator's position or at the security center. Each of the following plans shall be exercised annually prior to the month listed in each plan:
  - (a) Fire Safety Procedures Plan (to be exercised at any time during the year) shall include:
    1. Minor fires.
    2. Major fires.
    3. Fighting the fire.
    4. Evacuation procedures
    5. Staff functions by department and job assignment.
  - (b) Tornado/Severe Weather Procedures Plan (to be exercised prior to March) shall include:
    1. Staff duties by department and job assignment.
    2. Evacuation procedures.
  - (c) Bomb Threat Procedures Plan (to be exercised at any time during the year):
    1. Staff duties by department and job assignment.
    2. Search team, searching the premises.

(Rule 0940-5-42-.14, continued)

3. Notification of authorities.
  4. Location of suspicious objects.
  5. Evacuation procedures.
- (d) Flood Procedures Plan (to be exercised prior to March):
1. Staff duties by department and job assignment.
  2. Evacuation procedures.
  3. Safety procedures following the flood.
- (e) Severe Cold Weather (to be exercised prior to November) and Severe Hot Weather (to be exercised prior to May) Procedures Plans:
1. Staff duties by department and job assignment.
  2. Equipment failures.
  3. Insufficient HVAC on emergency power.
  4. Evacuation procedures.
  5. Emergency food service.
- (f) Earthquake Disaster Procedures Plan (to be exercised at any time during the year):
1. Staff duties by department and job assignment.
  2. Evacuation procedures.
  3. Safety procedures.
  4. Emergency services.
- (2) All facilities shall participate in the Tennessee Emergency Management local/county emergency plans on an annual basis. Participation includes but is not limited to filling out and submitting a questionnaire on a form to be provided by the Tennessee Emergency Management Agency. Documentation of participation must be maintained and shall be made available to survey staff as proof of participation.

**Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.